

REMARKS

Amendments to the Claims

Claims 1-20 are pending. The Applicants respectfully ask the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 1, 10, 15, 17 and 19 were amended. The Applicants hereby state that all amendments do not add new subject matter to the specification.

Claim Objections

The Examiner has objected to Claims 1, 10, 15 and 17 for claim informalities because each claim recites “with” when it appears that the claims should recite “which). The Applicants have amended Claims 1, 10, 15 and 17 to recite “which” and respectfully requests withdrawal of the objection.

Rejection Pursuant to 35 U.S.C. § 103(a) Obviousness

The Examiner has rejected Claims 1-20 as allegedly being obvious pursuant to 35 U.S.C. § 103(a) over Gary E. Borodic and Martin A. Acquadro, *Use of Botulinum Toxin for the Treatment of Chronic Facial Pain*, U.S. Patent Publication 2002/0192239 (Dec. 19, 2002), hereafter “the Borodic I publication” in view of Gary E. Borodic, *Controlled Administration of Chemodenervating Pharmaceuticals*, U.S. Patent No. 5,298,019 (May 29, 1994), hereafter “the Borodic II patent.”

The Examiner contends that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of these references and come up with a the presently claimed methods. Specifically, the Examiner argues that it would have been obvious to combine the administration of botulinum toxin for pain associated with post-operative incisional wound pain like dental extraction or reconstruction as taught by the Borodic I publication with a method of inhibiting tooth wear by administering botulinum toxin as taught by the Borodic II patent because the Borodic II

patent teaches that botulinum toxin can be injected into mastication muscles. The Applicants respectfully ask for reconsideration pursuant to 37 C.F.R. § 1.111.

Borodic I and Borodic II provide no motivation to combined references and come up with the methods of Claims 1, 10, 15 and 17

According to MPEP § 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Applicants respectfully submit that a *prima facie* obviousness case fails because the Borodic I publication and the Borodic II patent do not provide any motivation, suggestion or teaching that would lead a person of ordinary skill in the art to specifically develop methods of assisting dental procedures as presently claimed in Claims 1-18.

The presently claimed methods are directed, in part, toward assisting a dental procedure (Claim 1), facilitating an adherence of a dental item to a substrate in the mouth of a patient (Claim 10), facilitating adherence of a tooth to a substrate in the mouth of a patient (Claim 15), and accelerating adherence of a transplanted gum tissue to a substrate in the mouth of a patient (Claim 17). The methods encompassed by Claims 1, 10, 15 and 17 comprise, in part, an initial administration of a botulinum toxin followed by a subsequent dental procedure, therapy or treatment.

The Borodic I publication discloses a method of treating pain caused by trigeminal neuralgia (see. e.g., abstract, ¶ 5). The Borodic I publication classified trigeminal neuralgia as a chronic neuropathic facial pain involving a number of divergent etiologies, see, e.g., ¶ 2; ¶ 16; ¶ 23; ¶ 27; and ¶ 30. This publication discloses that one such cause of trigeminal neuralgia is dental extraction or reconstruction, see, e.g., ¶ 5. For example, a patient who undergoes dental extraction or reconstruction can develop trigeminal neuralgia if, e.g., the trigeminal nerve is damaged, compressed or underwent trauma, see, e.g., ¶ 5. The Borodic I publication also discloses a separate method for treating post-operative incisional wound pain (see. e.g., abstract, ¶ 6, Claim 13). Although this publication lists many surgical

procedures, see, e.g., ¶ 6, none of these procedures involve any dental procedures, let alone the dental procedures presently claimed. Additionally, both methods disclosed by the Borodic I publication teach that the administration of botulinum toxin occurs post-operatively and not pre-operatively. For example, the method of treating pain caused by trigeminal neuralgia requires that the patient be diagnosed with neuralgia before a botulinum toxin treatment can be administered, see, e.g., ¶ 4; ¶ 5; ¶ 16; and Claim 1. Likewise, the method for treating post-operative incisional wound pain expressly states that the botulinum toxin is administered post-operatively. See also, e.g., ¶ 6; and Claim 12. Lastly, both methods disclosed by the Borodic I publication teach that the only step in these methods is the administration of a botulinum toxin; there is no subsequent medical or dental procedure disclosed.

Thus, the Applicants respectfully submit that the disclosure covering of dental extraction or reconstruction in the Borodic I publication was as an underlying cause of trigeminal neuralgia and not as an affliction to be treated by botulinum toxin. In addition, the Borodic I publication taught the post-operative administration of a botulinum toxin to treat trigeminal neuralgia and incisional wound pain, and not as a pre-operative treatment for a dental procedure. Furthermore, the Borodic I publication is completely silent with regards to the use of a botulinum toxin in conjunction with another procedure, medical or dental. Thus, the Borodic II patent, at a minimum, needs to teach, suggest or motivate a person of ordinary skill in the art to 1) develop a dental procedure method; 2) develop a method for assisting a dental procedure; 3) use a botulinum toxin in conjunction with any other medical or dental procedure; 4) develop a method for assisting any dental procedure using a botulinum toxin; and 5) develop a method for facilitating adherence of a dental item, a tooth, or a transplanted gum tissue in the mouth of a patient using a botulinum toxin for a *prima facie* obviousness case can even be entertained.

The Borodic II patent discloses the use of a botulinum toxin to inhibit the involuntary grinding of teeth characterized by bruxism, see, e.g., col. 9, lines 30-32. Teeth grinding is not a dental procedure. At best this patent discloses the use of botulinum toxin to treat a symptom associated with bruxism. The Borodic II patent is silent with respect to a pre-operative use of a botulinum toxin in conjunction with another medical or dental procedure. Thus, this

disclosure does not teach, suggest or motivate a person of ordinary skill in the art to 1) develop a dental procedure method; 2) develop a method for assisting a dental procedure; 3) use a botulinum toxin in conjunction with any other medical or dental procedure; 4) develop a method for assisting any dental procedure using a botulinum toxin; and 5) develop a method for facilitating adherence of a dental item, a tooth, or a transplanted gum tissue in the mouth of a patient using a botulinum toxin. As such the Borodic II patent cannot make up for the teaching deficiencies present in the Borodic I publication and a *prima facie* case of obviousness cannot be made by the Examiner.

Borodic I and Borodic II provide no motivation to combined references and come up with the method of Claim 19

According to MPEP § 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Applicants respectfully submit that a *prima facie* obviousness case fails because the Borodic I publication and the Borodic II patent do not provide any motivation, suggestion or teaching that would lead a person of ordinary skill in the art to specifically develop the method of obtaining an optimal oral neuromuscular position in a patient as presently claimed in Claims 19-20.

The method of Claims 19 is directed, in part, toward obtaining an optimal oral neuromuscular position in a patient comprises the administration of a botulinum toxin. See also Example 1.

As discussed above, the Borodic I publication discloses a method of treating pain caused by neuralgia and a method for treating post-operative incisional wound pain by administering a botulinum toxin. As such, the Borodic I publication is completely silent with respect to any disclosure for a dental procedure method or the use of a botulinum toxin in such a method. Thus, the Borodic II patent, at a minimum, needs to teach, suggest or motivate a person of

ordinary skill in the art to 1) develop a dental procedure method; 2) use a botulinum toxin in a dental procedure method for a *prima facie* obviousness case can even be entertained.

As discussed above, the Borodic II patent discloses the use of a botulinum toxin to inhibit a symptom of bruxism and not the use of a botulinum toxin in a dental procedure. However, this disclosure does not teach, suggest or motivate a person of ordinary skill in the art to 1) develop a dental procedure method; 2) use a botulinum toxin in a dental procedure method. Thus, the Borodic II patent does not overcome any of the deficiencies of the Borodic I publication and a *prima facie* case of obviousness cannot be made by the Examiner.

Borodic I and Borodic II provide no motivation to combined references and come up with the method of Claims 6 and 14

According to MPEP § 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Applicants respectfully submit that a *prima facie* obviousness case fails because the Borodic I publication and the Borodic II patent do not provide any motivation, suggestion or teaching that would lead a person of ordinary skill in the art to specifically develop a period of time sufficient for the botulinum toxin to weaken the mastication muscle as presently claimed in Claims 19-20.

Claims 6 and 14 are directed, in part, toward waiting a period of time sufficient for a botulinum toxin to weaken the mastication muscle where that time period is from one hour to thirty days.

The Borodic I publication is completely silent with respect to the period of time sufficient for the botulinum toxin to weaken the mastication muscle. Thus, the Borodic II patent, at a minimum, needs to teach, suggest or motivate a person of ordinary skill in the art 1) what period of time is sufficient for a botulinum toxin to weaken the mastication muscle; 2) a time

period is from one hour to thirty days is sufficient for a botulinum toxin to weaken the mastication muscle for a *prima facie* obviousness case can even be entertained.

The Borodic II patent discloses the onset of dysphagia within 20 days of the injection of a botulinum toxin for the treatment of idiopathic spasmodic torticollis, see, col 7, line 61 through col. 8, line 29. This patent indicates that dysphagia, a swallowing disorder, is an unwanted side-effect caused by the diffusion of a botulinum toxin from the sternomastoid site of treatment to the muscles that control swallowing, see, col. 7, lines 63-66.

As such, the time period that the dysphagia side-effect appeared in certain patients suffering from idiopathic spasmodic torticollis treated with a botulinum toxin does not teach, suggest or motivate a person of ordinary skill in the art what period of time is sufficient for a botulinum toxin to weaken the mastication muscle before a follow-on dental procedure can be performed as presently claimed in Claims 6 and 14. As such the Borodic II patent cannot make up for the teaching deficiencies present in the Borodic I publication and a *prima facie* case of obviousness cannot be made by the Examiner.

Conclusion

For the reasons stated above, the Applicants respectfully submit that a *prima facie* case of obviousness cannot be made because the combined teachings of the Borodic I publication and the Borodic II patent do not provide any teaching, suggestion or motivation for a person of ordinary skill in the art to modify the methods disclosed in the Borodic I publication, as suggested by the Examiner, in order to derive the presently claimed method. Therefore, the Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) obviousness rejection for Claims 1-20.

CONCLUSION

For the above reasons the Applicants respectfully submit that the claims are in condition for allowance, and the Applicants respectfully urge the Examiner to issue a Notice to that effect. Should there be any questions, the Examiner is invited to call the undersigned agent.

Please use Deposit Account 01-0885 for the payment of any extension of time fees pursuant to 37 C.F.R. § 1.136 or any other fees due in connection with the current response.

Respectfully submitted,

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